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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,245	09/08/2003	Gary J. Mullen	GMMD-1-1002	8853

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EXAMINER

MCCORKLE, MELISSA A

ART UNIT PAPER NUMBER

3763

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/656,245	Applicant(s) MULLEN, GARY J.	
	Examiner Melissa A. McCorkle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-16 and 18-38 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 22 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4, 9-16, 18-20, 23-24, and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock (2003/0018309) in view of Shea (4,813,941). Breznock discloses applicant's basic inventive concept of an apparatus for treating pneumothorax and/or hemothorax, substantially as claimed with the exception of an adhesively coated tab configured to secure the hub of the device to the skin. Shea (4,813,941) shows this feature to be old in the medical art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity.

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4. Regarding claim 1, Breznock discloses a trocar with stylet and point for puncturing the body (fig 3A) and stopper (fig 3B); he also discloses a tube with lumen to receive stylet with open-ended portion and at least one fluid opening (fig 3B); he also demonstrates a hub and one-way valve continuous with lumens of tube and hub (fig 5A).

5. In regards to claims 2 and 23, Breznock discloses the point on the stylet extending beyond the proximal portion of the tube when said stylet is inserted into catheter assembly (fig 3B) and brings stopper into engagement with the hub.

6. Regarding claims 3 and 24, Breznock shows the diameter of the stopper to be larger than the diameter of the lumen of one-way valve (fig 3B).

7. Regarding claim 4, Breznock shows a portion of the stopper is removably retainable in at least a portion of the hub (fig 3B).

8. Regarding claims 9 & 28, Breznock shows an annular recess on outside wall of hub (fig 3B).

9. Regarding claims 10, 11, 29, Breznock shows one-way valve secured to hub by retaining ring position over said one-way valve within recess by at least one band and the adhesive tab is attached to band for securing the device to the patient (0015-0017).

10. Regarding claims 12 and 31, Shea discloses at least one tab including a removable covering (column 4 lines 4-6).

11. Regarding claims 13 and 30, Breznock discloses a disk coupled to catheter assembly for securing trocar to patient (0016).

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12. Regarding claims 14 and 32, Breznock discloses at least one of said stylet, catheter assembly, one-way valve and pull handle are comprised of radio-opaque material (0035).

13. Regarding claims 15 & 33, Breznock discloses a tube that includes a kink-resistant tube lumen wall (0010).

14. Regarding claims 16 & 18, and 34 & 35, 36, Breznock shows the kink-resistant lumen wall includes a first coiled monofilament polymer fiber (0003) and a second coiled monofilament fiber interwoven (0030).

15. Regarding claims 19 & 20, 34 & 37, Breznock shows the kink-resistant lumen wall including a first coiled monofilament metallic fiber (0030) interwoven with a second coiled monofilament metallic fiber (0030).

16. Regarding claim 38, Breznock shows the metallic fiber includes stainless steel (0030).

17. Claims 21 and 22 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea. Regarding claim 21, Breznock discloses a tube engaging a stylet, the tube having lumen with proximal and distal ports (fig 3B), a hub with proximal and distal face, the hub being attached to the tube, the lumen configured to form a passage for fluid continuous with tube lumen and dimensioned to receive a portion of stopper on stylet, in sealing engagement with tube lumen (3B), a one way valve in engagement with the hub distal face, the one-way valve configured so that the lumen is continuous with the passage hub lumen and tube lumen (3B). Shea (4,813,941) teaches an adhesive tab configured to draw and hold the hub in sealing

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engagement with the skin (column 4 lines 4-6). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Breznock to add the adhesive strips (column 4 lines 4-6) of Shea for the purpose of securing the hub of the device to the skin of the body cavity.

18. Regarding claim 22, Breznock also discloses a trocar obturator unit including the stylet with a point for puncturing the body, and a stopper coupled to stylet configured to position the stylet relative to catheter assembly (3B).

19. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea as applied to claims 1-4, 9-16, 18-24 and 28-38 above, and further in view of Ryan et al (5,693,031). Breznock in view of Shea disclose applicant's basic inventive concept of apparatus for treating pneumothorax and/or hemothorax substantially as claimed with the exception of the exterior of stopper or interior of one-way valve coated with a lubricant. Ryan et al shows this feature to be old in the medical devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Ryan et al to modify the apparatus of Breznock in view of Shea by adding lubricant (column 7 lines 55-60) to the exterior of stopper or interior of one-way valve so that the trocar is easily inserted into or removed from the catheter.

20. Claims 6-8 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breznock in view of Shea as applied to claims 1-4, 9-16, 18-24 and 28-38 above, and further in view of Calinog (3,703,899). Breznock in view of Shea disclose applicant's basic inventive concept of apparatus for treating pneumothorax and/or

hemothorax substantially as claimed with the exception of the device comprising a pull-handle attached to the stopper, wherein said pull handle is a ring or is a tab. Calinog shows this feature to be old in the medical devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Calinog to modify the apparatus of Breznock in view of Shea by adding a pull handle (fig 5) of Calinog to the stopper in order to provide handle for the user operate the device more effectively.

21. In regards to claims 6, 7, 8, 25, 26, and 27, Shea's pull handle (fig 5 #11) can be a ring (fig 5) or a tab (fig 5), wherein said ring may be construed as a tab.

Response to Arguments

22. Applicant's arguments filed 1/5/06 have been fully considered but they are not persuasive. Examiner contends that the extracorporeal fixation device is fixed once in position, thereby can be a fixed hub. In order to better secure the device to the patient, it would be obvious to look to Shea, whose device is used in the same function, for the use of adhesive strips. Furthermore, the office action does not intend to modify Breznock by removing the presence of the intracorporeal device, as applicant suggests. It merely states that it would be obvious to add the adhesive strips to the device to further secure the hub to the body. It is well known in the medical arts to fix medical devices to the body with tape or other adhesive means in order to better secure devices to the patient, therefore, one of ordinary skill in the art would look to adhesive means of Shea for better securing a device to a patient.

Conclusion

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23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,153,058 by Nehme discloses a Pleural Decompression Catheter. WO 95/18642 by Omirana discloses and Adhesive Surgical Retaining Device.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle
Examiner
Art Unit 3763

